Advice to the Inquiry into Hyponatraemia-related Deaths on Departmental Issues (Historic)

Comments on the Department's opening

Professor Gabriel Scally MB BCh BAO MSc DSc FFPH FFPH(I) FRCP MRCGP

3rd November 2013

Statement of interests: I was Chief Administrative Medical Officer and Director of Public Health of the Eastern Health and Social Services Board from 1989 to 1993. I have written and spoken extensively on clinical governance and this has included speaking engagements in Northern Ireland. I was a member of the General Medical Council from 1989 to 1999.

1. I believe that the comments of Mr McMillen (page 71 line 6) in relation to the origins of the current health service structures are rather misleading. When the Northern Ireland Health Service was established in 1948 there was one body established to run hospital services and it was the Northern Ireland Hospitals Authority. It is not entirely clear what are the 'regional health boards' referred to by Mr McMillen. If he means the four Health & Social Services Boards, they didn't come into being until 1973 with the demise of the Northern Ireland Hospitals Authority. He may of course be confusing Northern Ireland with England where there were Regional Hospitals Boards which were replaced by Regional Health Authorities in 1974. Scotland however did have Regional Hospital Boards which were established in 1948. In addition, where Mr McMillen says 'trusts' he may perhaps mean 'hospitals' as trusts did not exist in any part of the UK until they were ushered in by the UK-wide policy shift represented by the White Paper 'Working for Patients' in 1989.[1]

2. It is unfortunate that Mr McMillen confuses 'clinical governance' and 'regulation' in some of his remarks (page 71 line 18, to page 72 line 17). It seems, from his comments that he is asserting that 'clinical governance' and 'regulation' are the same thing. There are enormous differences. In relation to regulation, the Medical Act of 1858 introduced statutory regulation of the medical profession in the modern era. The Commission for Health Improvement (CHI), which was established by the Health Act 1999, was in fact an inspectorate rather than a regulator. It had no power to impose sanctions or remove the ability of an organisation to provide healthcare. What it did do was to judge the performance of trusts on what were sometimes called the seven pillars of clinical governance; namely patient involvement, risk management, clinical audit, staffing and management, education and training, clinical effectiveness and, finally, use of information.[2] The quote that Mr McMillen uses (page 72 lines 8 to 17) is a not entirely inaccurate depiction of CHI's role, which in any event only extended to England and Wales. This was despite section 22 of the Act specifically permitting it to extend its activities to Northern Ireland at the request of a Minister, that option was never, to my knowledge, exercised.

---

1 *Working for Patients.* HMSO. London, 1989.

2 Day, P. Klein, R. The NHS Improvers: A study of the Commission for Health Improvement. King's Fund. 2004 http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/nhs-improvers-study-commission-health-improvement-day-klein-feb04.pdf

3. In understanding the sequence of policy development and clinical governance it is important to note that several elements had been developed separately over time. For example, the Government's UK-wide White paper *Working for Patients* in 1989 established the expectation that all doctors would be participating in regular clinical audit activity. The systems and instruments for clinical audit developed substantially as a result but were often disconnected from other organisational processes that affected quality of care. The initiative to put a system around the often separate elements came with the Department of Health in London's White Paper, *The New NHS – Modern and Dependable*. It was published in December 1997 and contained the commitment that, 'In the new NHS … clinical governance arrangements will be developed in every NHS Trust to guarantee an emphasis on quality'.[3] The paper by Scally and Donaldson[4] was published in July 1998 and elaborated clinical governance to the clinical community through the pages of the British Medical Journal. It defined clinical governance as; 'a system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish'. Those words were carefully chosen and 'accountable' was an important inclusion. As the paper pointed out, 'In the future, well managed organisations will be those in which financial control, service performance, and clinical quality are fully integrated at every level'. It is very clear that clinical governance was about the overall culture and functioning of organisations, whether that involved clinical audit, training and recruitment of medical staff, patient complaints or clinical error.

4. Although the sequence in Mr McMillen's opening statement may indicate otherwise, the important 1999 paper on patient safety from the Institute of Medicine titled 'To Err is Human'[5] was published somewhat later than, rather than before, the clinical governance paper. It dealt with only one component of clinical governance, albeit an important one, namely 'that patients are safe from accidental injury'. It is, in my view, important not to confuse untoward incident reporting and the totality of clinical governance.

5. The impetus about untoward incident reporting arose from the recommendations of the 1994 Clothier Report into the case of Beverly Allitt. The lessons from the Allitt case were

[3] Department of Health. The New NHS – Modern and Dependable. London 1997

[4] Scally G and Donaldson LJ (1998) Clinical governance and the drive for quality improvement in the new NHS in England. Br Med J 317(7150) 4 July pp.61-65.

[5] Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. Washington, DC: National Academy Press, Institute of Medicine; 1999.

highly publicised throughout the UK. As I noted in paragraph 12 of my recent advice to the inquiry, there was, in England, an instruction to the Regional Directors of the NHS Executive in 1995 (I erroneously gave the year as 1994 in my text, although I did give the year as 1995 in the footnote) to put in place arrangements for the notification of serious untoward incidents. This communication came from the NHS Executive, which was an integral part of the Department of Health, and went to the Regional Directors of the NHS Executive, who were also civil servants and part of the Department of Health.

6. The average population covered by each of these regional offices was approximately six million people compared to the 1.6 million population of Northern Ireland. I respectfully suggest that Mr McMillen might be significantly underplaying things when he on page 87 line 18 describes the result of the central DH instruction as, 'a local reporting system set up in 1994'.

7. It was the data from the reporting systems established by these eight regional offices of the Department of Health's NHS Executive that is quoted in the 2000 report *An Organisation with A Memory* (Table 4.1). Unsurprisingly, Liam Donaldson being the Department of Health's Regional Director for one of the regions and having thus been responsible for establishing the reporting system in 1995, made use of his learning in compiling his report. In paragraph 4.17 of his report it outlines the four purposes of the systems established by the Department of Health in England in 1995 in each of its regional offices:

   Current regional incident reporting systems fulfil a number of purposes;

   - *creating an opportunity to make an intervention to resolve or handle a problem;*
   - *gathering information to learn from the adverse event and prevent similar occurrences in the future;*
   - *advising Health Ministers of the existence of the problem;*
   - *alerting government and NHS Press Officers that there is likely to be media coverage and advising on how this should be handled.*

   From this list it could be judged that if such a system had been established in Northern Ireland it might have made a contribution to preventing deaths from hyponatraemia.

8. As I noted in paragraph 15 of my recent advice to the Inquiry, the learning from several years of untoward incident reporting was that there was too much variation in reporting

and the processes need to be improved, standardised and, importantly, extended to include all 'near misses'. As it states in paragraph 4.18 of *Organisation with A Memory* one of the weaknesses was: '*The regional incident reporting systems undoubtedly miss some serious incidents and take hardly any account of less serious incidents or those which do not harm patients but might have done.*' It is the inclusion in future systems of less serious incidents and of near misses that is responsible for the very substantial increase in the estimates of incidents that might be reported.

9. I think perhaps Mr McMillen may not be aware that both in Northern Ireland and England the 'Management Executive' bodies were integral parts of the respective Departments of Health. Mr McMillen states on page 87 of his opening that;

> 'There's nothing in Sir Liam's Donaldson's paper that shows there was an reporting to the Department of Health other than by means of the old incident reporting matters, such as perioperative deaths and the failures of medical equipment.'

I would submit that Sir Liam's report, *An Organisation with A Memory*, shows entirely the opposite. It draws significantly upon learning from the 1998 untoward incident data submitted by the NHS in England to the Department's regional offices afoot of the 1995 instruction to establish such systems. Unsurprisingly, the conclusion was that much more progress, including standardisation and unification across England, was necessary. The recommendations were accepted and implemented.

10. I will not play out in detail the massive organisational upheaval taking place in the English NHS and the Department of Health in London over the time span in question, suffice it to say that it is a mark of the importance of the issues involved that such a consistent effort to improve quality of care was achieved. The changes over time within Northern Ireland were concentrated at the level of Government structures and the Department, Boards and Trusts remained remarkably stable and should therefore, in my view, been able to match, if not exceed, the pace of development of initiatives around quality seen elsewhere in the UK. Mr McMillen expresses this very accurately and succinctly in his opening (page 93 lines 7-11):

> 'Again, it's one of the functions of the smaller population and a smaller geographical area that we can perhaps act slightly more rapidly and close the gap …'

11. With all due respect to Mr McMillen's argumentation, I hold that it is evident that this early implementation of untoward incident reporting in England, its review in 2000 via *An Organisation with A Memory* and the consequent recommendations for changes to extend and improve the system, stands in considerable contrast with the position in Northern Ireland as enunciated by Mr McMillen on page 92 of his opening:

> 'Indeed, in Northern Ireland we had our first guidance as to adverse incident reporting -- it came in July 2004 and it was followed up by means of a circular in 2006, and additional guidance has been given on classification by another circular, again in 2006'.

12. As I touched on previously, one cannot of course be certain that any hyponatraemia death might have been reported via a system, if the Department in Northern Ireland had established one after the Clothier report, but there would at least have been a reporting system in place and an expectation that reports would be made.

13. The differential in progress in achieving a system for reporting of serious untoward incidents is, as I have stated, one element in a lagging behind in respect of clinical governance issues as a whole. The 2003 report from the national Audit Office shows this clearly not just in the main report, but also in Appendix 5 where they describe progress in Northern Ireland, Scotland and Wales.[6] In Scotland guidance on clinical governance had been issued by the CMO and CNO in 1998 and, to quote the report;

> 'The Clinical Standards Board for Scotland had the remit to develop and run a national system of quality assurance of clinical services. In partnership with healthcare professionals and members of the public, it set standards for clinical services, assessed performance throughout NHS Scotland against those standards and published the findings. Two rounds of visits to each trust to assess performance against generic - clinical governance - standards have been completed'.

In contrast the section on Northern Ireland the issuing of the guidance in 2003 is noted and there are descriptions on what action will happen in the future.

[6] National Audit Office. Achieving Improvements through Clinical Governance A Progress Report on Implementation by NHS Trusts. Report by the Comptroller and Auditor General HC 1055 Session 2002-2003: 17 September 2003 http://www.nao.org.uk/wp-content/uploads/2003/09/02031055.pdf

Responsibilities of the chief professional officers of the Department

14. I note Mr McMillen's statement on page 97 that neither the Chief Medical Officer nor the Chief Nursing Officer had direct policy responsibility for quality or clinical governance within the department at the relevant time. It is not clear from Mr McMillen's remark whether that was because nobody in the Department had such policy responsibility or because the responsibility was located elsewhere within the structures of the department. I respectfully suggest that there is little in Mr McMillen's opening remarks to suggest that the Department as a whole took responsibility for the quality of patient care. As for responsibility for clinical governance, it is a frequent occurrence that an emergent policy direction may not have a specified locus within a Department of government and it may be some time before it is consolidated into role specifications. It is, however, not unreasonable to assume, and indeed expect, that the clinical professionals in the Department would be driving on clinical governance. Indeed Mr McMillen references several initiatives on behalf of the CMO. There is of course a separate professional duty arising from their professional registration that should provide the CMO and CNO with an imperative to take action to improve quality of care.

15. In his opening remarks (page 97) Mr McMillen states that:

> 'Both officers, and the CMO in particular, would have a professional advisory role, ensuring that things within their purview remained central to the department's policy and strategic direction'.

In my recent advice (para 54) to the Inquiry I ventured that one reason for the apparent ineffectiveness of the chief professional officers may have arisen from the positioning and resourcing of the key professional posts within the structures of the time. Given the above remarks on behalf of the Department it would appear that the ability or inability of the chief professional officers to make an effective contribution to the development of policy and its implementation would merit exploration. The Chief Medical Officer's contribution in Northern Ireland would, on the face of it and in respect of the issues of clinical governance, appear to be distinctly different to the effectiveness of the Chief Medical Officer role as carried out in England as evidenced by the leadership given on clinical governance by the CMO of England and, indeed the CMO for Scotland. If the Northern Ireland CMO was, in Mr McMillen's words, 'asking that things be done as a matter of

urgency' it would be important to know why this did not happen. It is unfortunately not unknown for Chief Medical Officers, or their equivalent in other health systems, to face unacceptable restraints to what they may say and do in the context of their role.[7]

Reporting and accountability to the Department

16. I note the comments of Mr McMillen in respect of accountability between health service bodies and the department. I hold firm to the view that there is management accountability running between the Boards of trusts and the Department. As I understand it the Department disagrees and that their position, as enunciated by Mr McMillen (page 108 lines 10-12) is that:

> 'It is not management accountability; in our submission, it's strategic and public interest concerns'.

17. The assertion that the Department did not exercise 'management accountability' in relation to the health service appears not to be in keeping with the structure and operation of the Department during much of the period in question. Most markedly it does not appear to be compatible with the creation and operation within the Department of Health of the Health & Personal Social Services Management Executive. The HPSS Management Plan for 1995/6 – 1997/8 quotes the seven main objectives of the Management Executive of the Department. The second of these is: 'To set and ensure the achievement of precise objectives and targets for the health and personal social services in accordance with national and regional policies and priorities.'[8] This management plan outlines the key objectives for the period, including, 'raising standards, improving quality and making services more responsive to the needs of individuals …'. It also includes a requirement for health and social care providers to work on issues such as clinical audit and clinical outcomes. The Management plan goes into significant detail in relation to the performance of individual clinical specialties in relation to targets for throughputs and day case percentages.

18. It is notable that it was the NHS Executive as part of the Department of Health in London (i.e. the equivalent of the H&PSS Management Executive in Northern Ireland) that sent

[7] Scally, G. Chief medical officers: the need for public health at the heart of government. BMJ 2013;346:f688 http://www.bmj.com/highwire/filestream/629233/field_highwire_article_pdf/0/bmj.f688

[8] Health & Personal social Services management Executive. HPSS Management Plan 1995/6 – 1997/8 Ref: 306-083-003

out the instruction to establish serious untoward incident reporting systems across England in 1995.[9] The Department's management relationship with health service providers in Northern Ireland did not end with disappearance of its management executive. Indeed the 2003 Departmental circular providing guidelines for the implementation of clinical governance was issued from the Department's Planning and Performance Management Directorate.

19. Even in the unlikely case that the above does not represent the exercise of considerable management accountability, the alternative position, characterised by Mr McMillen (page 108 line 25) as 'general strategic oversight', does not appear to me to be congruent with the formal, though limited, reporting mechanisms operated by the Department for the notification to them of adverse incidents in relation to medical devices, equipment, buildings, plant and pharmaceuticals. Nor indeed for the reporting requirement promulgated by the Department in 1997 in relation to notification to them of incidents in respect to patients in mental health institutions or with learning disabilities. (I noted this in paragraph 6 of my recent advice.) With all due respect to Mr McMillen, these mechanisms do not appear to be within the realm of 'strategic and public interest concerns'.

[9] Letter to NHS Executive Regional Directors from J.F.Shaw, Director of Corporate Affairs, NHS Executive, 10 May 1995

Chief medical officers: the need for public health at the heart of government

BMJ 2013; 346 doi: http://dx.doi.org/10.1136/bmj.f688 (Published 5 February 2013)
Cite this as: BMJ 2013;346:f688

- **Article**
- **Related content**
- **Read responses (3)**
- **Article metrics**

Gabriel Scally, *director, WHO Collaborating Centre for Healthy Urban Environments, University of the West of England*

gabriel.scally@btinternet.com

As the global economic crisis continues to have detrimental effects on health and health services around the world, there has never been a greater need for powerful advocates for public health at the heart of government. The need for an articulate and authoritative voice that can tell elected politicians the potential health consequences of their actions and inactions has been recognised in many democracies since the pinnacle of the sanitary revolution of the 19th century.

Many countries around the world have such a post designated in their governmental structures to provide expert advice on current and potential hazards to public health. There is, however, enormous variation in how this national role is positioned. In the countries of the European Union it ranges from a top level office occupied by a public health physician to a post at a lower level of government, or even separate from it, and occupied by an administrator rather than a physician.[1]

Perhaps the two most prominent posts globally are the surgeon general of the United States and the chief medical officer (CMO) of England, which incorporates the role of chief medical adviser to the UK government. These two posts show the advantages and hazards of having a medical voice so close to the heart of government.

There has been a surgeon general in the US since 1871. He or she is an officer in the US Public Health Service, and the holder is appointed by, and serves at, the pleasure of the president. Although lacking substantial power, the post has traditionally had a high profile and carries a public expectation of championing public health goals and aspirations.

The close connection with the political process can lead to conflict if the surgeon general's views meet with the disapproval of the president. Bill Clinton sacked Joycelyn Elders, the 15th surgeon general, after a series of controversial statements on sexual health.[2] Even more tellingly, at a hearing of a House of

Representatives committee in 2007, three former surgeons general gave testimony of a culture of political interference in their role.[3] Richard Carmona, who served President George W Bush, experienced the most extreme professional repression, he told the House Committee on Oversight and Government Reform in 2007. He was regularly told what he should or should not say and had his reports censored and suppressed. He was even instructed not to prepare reports on mental health, emergency preparedness, and global health.

The history of the CMO in England stretches back to 1855, when John Simon was appointed medical officer to the Board of Health in response to the threat of cholera.[4]Simon used his considerable political skills to establish his freedom of speech and his access to ministers and the machinery of government. Despite being the driving force behind many pieces of public health legislation that laid the foundations of the improvement in population mortality, even Simon was eventually marginalised and resigned.[5] The post, however, has remained: it is a high level civil service post, and now has its 16th holder. Sir Liam Donaldson, the 15th CMO, broke new ground as a senior civil servant by making public his disagreement with the government on the subject of control of environmental tobacco smoke, and by surviving in office with even greater influence. His robust approach to protecting the public's health won the day. He combined this independence of view with helping the government develop important policies on health and healthcare. Historically, the best CMOs have been willing to speak publicly without fear or favour but often also did so behind closed doors, where tough arguments with recalcitrant or ideologically dogged ministers needed to be won. This strength often garnered respect, sometimes, ironically, from politicians who received praise for taking the firm public health action on which they were reluctant to embark (smoke-free legislation in England is a good example of this).[6] Perhaps though, strength and fearlessness are not to the taste of all political administrations. Donaldson's successor was appointed on a short term contract to a post diluted by being combined with the role of director general of research and development (a demanding portfolio in its own right with extensive international commitments) and is one of the few English CMOs to have no public health background.

Even more curious is the UK government's decision to appoint a medical scientist to the post of chief scientific adviser. This seems a recipe for conflict, misunderstanding, and confusion, particularly in giving advice to the public on aspects of health risk and also in the handling of emergencies, where both CMO and chief scientific adviser sit around the COBRA table to guide ministers' decisions. In the past, distinguished non-medical scientists have held the latter post and complemented very well the CMO's role and responsibilities. It remains to be seen whether the nation can have two doctors, especially if they disagree in public, say, on vaccination policy.

The challenges set by landmark reports on social determinants of health in the UK and globally should presage a broadening in health thinking that is, in its way, equivalent to the sanitarian movement that shifted the focus from care to prevention in the 19th century.[7] [8] For this reorientation to succeed even partially requires outspoken public advocacy at local, national, and international level. The role of CMO at national level as an empowered advocate of population health should be promoted by the World Health Organization as an essential component of good health governance for the 21st century.

Towards the end of Bertold Brecht's play *Life of Galileo*, Galileo says: "Unhappy is the land that needs a hero."[9] The state of global health is such as to indicate clearly that we are in desperate need of passionate public health heroes at the heart of national governments around the world.

Notes

Cite this as: *BMJ* 2013;346:f688

Footnotes

Competing interests: The author was a candidate for the chief medical officer of England in 2011.

Provenance and peer review: Not commissioned; not externally peer reviewed.

References

1. Jakubowski J, Martin-Moreno JM, McKee M. The governments' doctors: the roles and responsibilities of chief medical officers in the European Union. Clin Med2010;10:560–2.

Abstract/FREE Full Text

2. Richter P, Cimons M. Clinton fires surgeon general over new flap. LA Times1994 Dec 10. http://articles.latimes.com/1994-12-10/news/mn-7305_1_surgeon-general.
3. The surgeon general's vital mission: challenges for the future. Hearing before the Committee on Oversight and Government Reform House of Representatives. July 10 2007. US Government Printing Office, 2008. https://house.resource.org/110/gov.house.ogr.20070710_hrs15REF2154.pdf.
4. Sheard S, Donaldson LJ. The nation's doctor: the role of the chief medical officer 1855-1998. Radcliffe, 2005.
5. Lambert R. Sir John Simon 1816-1904 and English social administration. McGibbon Kee, 1963.
6. Institute for Government: reducing smoking rates policy reunion. Seminar report, 9 May 2011. www.instituteforgovernment.org.uk/sites/default/files/policy_seminar_report_smoking.pdf.
7. Fair society, healthy lives (the Marmot review). Department of Health, 2010.
8. Commission on Social Determinants of Health. CSDH final report: closing the gap in a generation: health equity through action on the social determinants of health. World Health Organization, 2008.
9. Brecht B. Life of Galileo. Eyre Methuen, 1980.